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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,277	10/22/2001	Jeffrey S. Flier	1440.1042-004	9612

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EXAMINER

BYRD, DEVON R

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/040,277	FLIER ET AL.	
	Examiner Devon R Byrd	Art Unit 1639	<i>FILE COPY</i>
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>22 October 2001</u> .			
2a) <input type="checkbox"/> This action is <b>FINAL</b> .		2b) <input type="checkbox"/> This action is non-final.	
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-25</u> is/are pending in the application.			
4a) Of the above claim(s) _____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.			
6) <input type="checkbox"/> Claim(s) _____ is/are rejected.			
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.			
8) <input checked="" type="checkbox"/> Claim(s) <u>1-25</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of:			
1. <input type="checkbox"/> Certified copies of the priority documents have been received.			
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.			
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.		6) <input type="checkbox"/> Other: _____.	

## **DETAILED ACTION**

### **Status of the Claims**

Claims 1-25 are pending in the present application and are subject to restriction and election of species requirements.

#### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, drawn to a method of modulating ciliary neurotrophic factor cell signaling activity by inhibition of SOCS-3 activity, classified in class 435, subclass 375.
- II. Claims 11-13, drawn to a cell line comprising a cytokine receptor and a reporter gene construct, classified in class 435, subclass 69.1.
- III. Claim 14, drawn to a method for identifying SOCS-3 inhibitors, classified in class 435, subclass 7.71.
- IV. Claims 15 and 19, drawn to a SOCS-3 inhibitor, classified in class 435, subclass 7.71.
- V. Claims 16 and 17, drawn to a ciliary neurotrophic factor responsive cell line, classified in class 435, subclass 325.
- VI. Claim 18, drawn to a method for identifying SOCS-3 inhibitors, classified in class 435, subclass 386.
- VII. Claims 20 and 21, drawn to a method of reducing weight or food intake in a mammal, classified in class 514, subclass 909.

VIII. Claims 22 and 23, drawn to a method of preventing or inhibiting neurodegeneration in a mammal, classified in class 514, subclass 903.

IX. Claims 24 and 25, drawn to a method of increasing weight or food intake in a mammal, classified in class 426, subclass 2.

Although there are no provisions under the section for “Relationship of Inventions” in MPEP § 806.05 for inventive groups that are directed to different methods, restriction is deemed proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I, III, and VI-IX are directed to methods that recite structurally and functionally distinct elements, are not required for one another, and achieve different goals. Group I requires the SOCS-3 target protein JAK2, which is not required for any of the other groups. Group III requires an organic molecule library, which is not required for any of the other groups. Group V requires the presence of IL-3, which is not required for any of the other groups. Groups VI-IX require administering a substance to a mammal, which is not required for Groups I and III. Group VII requires the reduction of weight or food intake of a mammal, which is not required for any of the other groups. Group VIII requires the prevention or inhibition of neurodegeneration, which is not required for any of the other groups. Group IX requires increasing the weight or food intake of a mammal, which is not required for any of the other groups. Therefore a search and examination of all four methods in one patent application would result in an undue burden, since the subject matter, and literature and sequence searches for the three methods are divergent.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for inventive groups that are directed to different products, restriction is deemed proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups II, IV and V are directed to products that are distinct both physically and functionally, are not required for one another, and are therefore patentably distinct. The cell line of Group II requires a reporter gene construct, which is not required for Groups IV or V. Group V requires that the cell line be dependent upon a second cytokine for growth, which is not required for Groups II or IV. Therefore a search and examination of the three products in one patent application would result in an undue burden, since the subject matter, and literature and sequence searches for the three methods are divergent.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with another materially different product such as a cell line lacking a reporter gene construct, and SOCS-3 mRNA levels are directly measured using labeled hybridization probes.

Inventions II and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product can be used to detect ligands that result in SOCS-3 production, as claimed.

Inventions II and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to detect ligands that result in SOCS-3 production, as claimed.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as identifying modulators of cellular components other than SOCS-3.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be used with a cell line that does not comprise a reporter gene construct.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be used with a cell line that is not dependent upon a second cytokine for growth.

Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be used with a cell line that is not dependent upon a second cytokine for growth.

**Because these inventions are distinct for the reasons given above, and**

- a. have acquired a separate status in the art as shown by their different classification;
- b. have different and separately burdensome manual and/or computer structure, name, and bibliographical searches; and,
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

***Election of Species (Groups I-IX)***

This application contains claims directed to the following patentably distinct species of the claimed invention:

- a) [a] SOCS-3 antisense nucleotide (e.g., as disclosed on p 31, Example 2)

- b) a modified SOCS-3 polypeptide, (e.g., as disclosed on p 12, lns 6-18)
- c) a SOCS-3 inhibitor
- d) a SOCS-3 target protein
- e) a cell line as disclosed on p 15, ln 29 (e.g., CHO, Ba/F3, HepG2, H35-hepatoma cells) and p 30, ln 25 (e.g., astrocytes)
- f) a cytokine receptor as disclosed on p 16, lns 4 and 5 (e.g., CNTF receptor)
- g) a reporter gene as disclosed on p 14, lns 16 and 17 (e.g., CAT, luciferase,  $\beta$ -galactosidase)
- h) a cognate ligand
- i) an organic molecule library
- j) a cDNA expression library
- k) an effective amount of a SOCS-3 inhibitor

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Devon R Byrd whose telephone number is 703-305-0159. The examiner can normally be reached on Mon-Fri 8a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-2317. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

DB

September 3, 2003

BENNETT CELSA  
PRIMARY EXAMINER

